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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,679	02/04/2002	Robert E. Fischell	A2-01	1598

7590 12/31/2007

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EXAMINER
HOLMES, REX R

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/061,679	FISCHELL ET AL.	
	Examiner	Art Unit	
	Rex Holmes	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable Fischell et al. (U.S. Pat. 6,112,116) further in view of Thompson (U.S. Pat. 6,571,125)

4. Fischell discloses the claimed invention including warning and then injecting a thrombolytic or anti-thrombogenic agent into the bloodstream in response to a heart attack (See ABSTRACT; Col. 1, ll. 40-48). Although silent as to the pre-implantation requirements, it is inherent that a physician would look at several, if not all, of the factors claimed prior to determining patient need, and if not inherent it would have been obvious to those in the art at the time of the invention to have looked at any patient

history considerations necessary prior to performing an invasive implant surgical technique for diagnosis and/or therapy.

5. Thompson teaches a implantable medical device that is implanted in a person of risk (e.g. Col. 1) that senses cardiac, blood or cardiovascular parameters (e.g. Col. 6, ll. 1-10), a drug port that allows for the patient to inject medication that includes thombolytic medication into the cardio saver device (e.g. Col. 8, ll. 46-53). Thompson further discloses that the thombolytic medication includes tPA (e.g. Col. 6, ll. 10-24). Thompson further discloses therapies may be useful in preventing or lessening the severity of a stroke and that the drug therapy is administered in response to fibrillation (Col. 7, ll. 21-36).

6. Regarding claims 1 and 3-5, Fischell discloses the claimed invention but fails to disclose a drug port to allow for the patient to inject medication into the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Fischell, with a drug port as taught by Thompson, since such a port would provide the system with a means for supplying the device with medication and would provide the predictable result of allowing the patient to inject and supply medication at times when medication is needed.

7. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable Fischell et al. (U.S. Pat. 6,112,116) further in view of Zacouto (U.S. Pat. 5,305,745).

8. Fischell discloses the claimed invention including warning and then injecting a thrombolytic or anti-thrombogenic agent into the bloodstream in response to a heart attack (See ABSTRACT; Col. 1, ll. 40-48). Although silent as to the pre-implantation

requirements, it is inherent that a physician would look at several, if not all, of the factors claimed prior to determining patient need, and if not inherent it would have been obvious to those in the art at the time of the invention to have looked at any patient history considerations necessary prior to performing an invasive implant surgical technique for diagnosis and/or therapy.

9. Zacouto teaches that it is known to use an audible patent warning system to warn the patient of danger before the device delivers the delivery of thrombogenic medication heparin either automatically or by hand as set forth in Column 23, lines 3-26, Column 39, lines 44-51 to provide corrected effects to coagulation.

10. Regarding claims 1 and 3-5, Fischell discloses the claimed invention but fails to disclose a drug port to allow for the patient to inject medication into the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Fischell, with a drug port as taught by Zacouto for either automatically injecting or injecting by hand, since such a port would provide the system with a means for supplying the device with medication and would provide the predictable result of allowing the patient to inject and supply medication at times when medication is needed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rex Holmes
Examiner
Art Unit 3762

George Evanisko
Primary Examiner
Art Unit 3762

12/26/7